

AMENDMENT TO DRAWINGS

The sheet of drawings attached as part of the Appendix includes new Figures 11 and 12, which have been added to address an objection by the Examiner.

REMARKS***Summary of the Amendment***

Upon entry of the above amendment, the specification and claims 1 and 19 will have been amended and new Figures 11 and 12 will have been submitted for consideration by the Examiner. Accordingly, claims 1 – 23 currently remain pending.

Summary of the Official Action

In the instant Office Action, the Examiner has objected to the drawings, rejected claims 15 – 17 as non-statutory subject matter, and rejected claims 1 – 23 over the art of record. By the present amendment and remarks, Applicants submit that the objections and rejections have been overcome, and respectfully request reconsideration of the outstanding Office Action and allowance of the present application.

Traversal of Drawing Objection Under 37 C.F.R. 1.83(a)

Applicants traverse the objection to the drawings under 37 C.F.R. 1.83(a) as failing to show each recited feature of the claims.

By the present amendment, Applicants submit herewith new Figures 11 and 12 to show the features of claims 11 and 8, respectively. Accordingly, consideration of these new Figures and withdrawal of the objection is requested.

However, as claims 16, 17, 22, and 23 are process claims, which recite process features, not individual elements. Accordingly, Applicants submit that the originally submitted drawings, as well as the disclosure in paragraph [0028] provide sufficient disclosure to one ordinarily skilled in the art to make and/or use

the invention without undue experimentation, and that further illustration is not necessary to facilitate the understanding of the artisan.

Therefore, Applicants request withdrawal of the drawing objection, and an indication that the pending drawings, including new Figures 11 and 12, are acceptable.

Traversal of Rejection Under 35 U.S.C. § 101

Applicants traverse the rejection of claims 15 – 17 under 35 U.S.C. § 101 as failing to clearly recite a process or apparatus.

Applicants note that claims 15 – 17 are process claims directed to the insertion of the lachrymal plug described in at least independent claim 1. Thus, while the dependency on independent claim 1 provides a shorthand in the claim's preamble for describing the lachrymal plug to be inserted, it is apparent that each recited feature following the phrase "the process comprising:" is directed to the process of inserting the lachrymal plug. Thus, it is clear that the claim is directed to a process and that each recited feature is directed to the process.

Therefore, Applicants request that the Examiner reconsider and withdraw the rejection of claims 15 – 17 under 35 U.S.C. § 101 and indicate that these claims are fully in compliance with the statute.

Traversal of Rejection Under 35 U.S.C. § 102(b)

1. Over McKeen

Applicants traverse the rejection of claims 1 – 4, 7 – 11, 15, and 18 – 21 under 35 U.S.C. § 102(b) as being anticipated by McKEEN et al. (U.S. Patent No. 4,915,684) [hereinafter "McKEEN"].

Applicants independent claim 1, as currently amended, recites, *inter alia*, a substantially cylindrical body having an external lateral wall, and flexible elements attached to the external wall *structured and arranged to straighten out when positioned* to maintain said lachrymal plug in position. Applicants' independent claim 19, as currently amended, recites, *inter alia*, positioning in a lachrymal duct a substantially cylindrical body having external lateral wall and flexible elements attached to the external wall *structured and arranged to straighten out when positioned* to maintain the lachrymal plug. Applicants submit that McKEEN fails to show at least the above-noted features.

While McKEEN shows a device for modulating flow of lachrymal fluid, which includes an arcuate head, a cylinder, and a peripheral member, Applicants note that there is no disclosure that these devices include flexible elements, as recited in at least independent claims 1 and 19. Moreover, Applicants submit that there is no disclosure of flexible elements structured and arranged to straighten out to maintain the position of the plug.

Because McKEEN fails to show at least the above-noted features, Applicants submit that the applied art fails to disclose each and every recited feature of the claims. Therefore, Applicants submit that the applied art fails to provide an adequate evidentiary basis to support a rejection of anticipation under 35 U.S.C. § 102(b), and that the present rejection is improper and should be withdrawn.

Further, Applicants submit that claims 2 – 4, 7 – 11, 15, 18, 20, and 21 are allowable at least for the reason that each of these claims depend from an

allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claims 1 – 4, 7 – 11, 15, and 18 – 21 and indicate that these claims are allowable.

2. Over Guena

Applicants traverse the rejection of claims 1 – 4, 7 – 11, 15, and 18 – 21 under 35 U.S.C. § 102(b) as being anticipated by GUENA et al. (U.S. Patent No. 5,417,651) [hereinafter “GUENA”].

Applicants independent claim 1, as currently amended, recites, *inter alia*, a substantially cylindrical body having an external lateral wall, and flexible elements attached to the external wall *structured and arranged to straighten out when positioned* to maintain said lachrymal plug in position. Applicants’ independent claim 19, as currently amended, recites, *inter alia*, positioning in a lachrymal duct a substantially cylindrical body having external lateral wall and flexible elements attached to the external wall *structured and arranged to straighten out when positioned* to maintain the lachrymal plug. Applicants submit that GUENA fails to show at least the above-noted features.

While GUENA shows a punctum plug, which includes an flat head, a neck, and a bulb or umbrella, in which only the bulb is arguably disclosed as flexible, Applicants note that there is no disclosure of the recited *flexible elements*, as recited in at least independent claims 1 and 19. Moreover, Applicants submit

that there is no disclosure of flexible elements structured and arranged to straighten out to maintain the position of the plug.

Because GUENA fails to show at least the above-noted features, Applicants submit that the applied art fails to disclose each and every recited feature of the claims. Therefore, Applicants submit that the applied art fails to provide an adequate evidentiary basis to support a rejection of anticipation under 35 U.S.C. § 102(b), and that the present rejection is improper and should be withdrawn.

Further, Applicants submit that claims 2 – 4, 7 – 11, 15, 18, 20, and 21 are allowable at least for the reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claims 1 – 4, 7 – 11, 15, and 18 – 21 and indicate that these claims are allowable.

Traversal of Rejection Under 35 U.S.C. § 103(a)

1. *Over McKeen in view of Freeman*

Applicants traverse the rejection of claims 12 and 13 under 35 U.S.C. § 103(a) as being unpatentable over McKEEN in view of FREEMAN (U.S. Patent No. 3,949,750).

As noted above, McKEEN fails to disclose flexible elements and flexible elements *structured and arranged to straighten out when positioned*. Further,

Applicants note that McKEEN likewise fails to provide any teaching or suggestion of forming the peripheral members as flexible elements.

Likewise, Applicants submit that, while FREEMAN discloses a punctum plug, there is no teaching or suggestion of flexible elements, as recited in at least independent claim 1, nor is there any teaching or suggestion for forming the tips or barb portions as flexible elements *structured and arranged to straighten out when positioned* to maintain the position of the plug, as recited in at least independent claim 1.

Because neither document teaches or suggests at least the above-noted feature of at least independent claim 1, Applicants submit that no proper combination of these documents can render unpatentable the instant invention.

Further, Applicants submit that claims 12 and 13 are allowable at least for the reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claims 12 and 13 and indicate that these claims are allowable.

2. Over Guena in view of Freeman

Applicants traverse the rejection of claims 12 and 13 under 35 U.S.C. § 103(a) as being unpatentable over GUENA in view of FREEMAN.

As noted above, GUENA fails to disclose flexible elements and/or flexible elements *structured and arranged to straighten out when positioned* to maintain a

position of the plug. Further, Applicants note that GUENA likewise fails to provide any teaching or suggestion of forming the device with flexible elements.

Likewise, Applicants submit that, while FREEMAN discloses a punctum plug, there is no teaching or suggestion of flexible elements, as recited in at least independent claim 1, nor is there any teaching or suggestion for forming the tips or barb portions as flexible elements structured and arranged to straighten out when positioned to maintain the position of the plug, as recited in at least independent claim 1.

Because neither document teaches or suggests at least the above-noted feature of at least independent claim 1, Applicants submit that no proper combination of these documents can render unpatentable the instant invention.

Further, Applicants submit that claims 12 and 13 are allowable at least for the reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claims 12 and 13 and indicate that these claims are allowable.

3. Over McKeen in view of Herrick

Applicants traverse the rejection of claim 14 under 35 U.S.C. § 103(a) as being unpatentable over McKEEN in view of HERRICK (U.S. Patent No. 5,163,959).

As noted above, McKEEN fails to disclose flexible elements and flexible elements structured and arranged to straighten out when positioned to maintain a

position of the plug. Further, Applicants note that McKEEN likewise fails to provide any teaching or suggestion of forming the peripheral members as flexible elements.

Likewise, Applicants submit that, while HERRICK discloses a canalicular implant, there is no teaching or suggestion of flexible elements, as recited in at least independent claim 1, nor is there any teaching or suggestion for forming the tips or barb portions as flexible elements structured and arranged to straighten out when positioned to maintain a position of the plug, as recited in at least independent claim 1.

Because neither document teaches or suggests at least the above-noted feature of at least independent claim 1, Applicants submit that no proper combination of these documents can render unpatentable the instant invention.

Further, Applicants submit that claim 14 is allowable at least for the reason that it depends from an allowable base claim and because it further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claim 14 and indicate that these claims are allowable.

4. Over Guena in view of Herrick

Applicants traverse the rejection of claim 14 under 35 U.S.C. § 103(a) as being unpatentable over GUENA in view of HERRICK.

As noted above, GUENA fails to disclose flexible elements and/or flexible elements structured and arranged to straighten out when positioned to maintain a

position of the plug. Further, Applicants note that GUENA likewise fails to provide any teaching or suggestion of forming the device with flexible elements.

Likewise, Applicants submit that, while HERRICK discloses a canalicular implant, there is no teaching or suggestion of flexible elements, as recited in at least independent claim 1, nor is there any teaching or suggestion for forming the tips or barb portions as flexible elements structured and arranged to straighten out when positioned to maintain a position of the plug, as recited in at least independent claim 1.

Because neither document teaches or suggests at least the above-noted feature of at least independent claim 1, Applicants submit that no proper combination of these documents can render unpatentable the instant invention.

Further, Applicants submit that claim 14 is allowable at least for the reason that it depends from an allowable base claim and because it further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claim 14 and indicate that these claims are allowable.

5. Over McKeen in view of Seder

Applicants traverse the rejection of claims 16, 17, 22, and 23 under 35 U.S.C. § 103(a) as being unpatentable over McKEEN in view of SEDER et al. (U.S. Patent No. 4,959,048) [hereinafter "SEDER"].

As noted above, McKEEN fails to disclose flexible elements and flexible elements structured and arranged to straighten out when positioned to maintain a position of the plug. Further, Applicants note that McKEEN likewise fails to

provide any teaching or suggestion of forming the peripheral members as flexible elements.

Likewise, Applicants submit that, while SEDER discloses a lacrimal duct occluder, there is no teaching or suggestion of flexible elements, as recited in at least independent claim 1, nor is there any teaching or suggestion of structuring and arranging flexible elements to straighten out when positioned to maintain a position of the plug, as recited in at least independent claims 1 and 19.

Because neither document teaches or suggests at least the above-noted feature of at least independent claims 1 and 19, Applicants submit that no proper combination of these documents can render unpatentable the instant invention.

Further, Applicants submit that claims 16, 17, 22, and 23 are allowable at least for the reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claims 16, 17, 22, and 23 and indicate that these claims are allowable.

6. Over Guena in view of Seder

Applicants traverse the rejection of claims 16, 17, 22, and 23 under 35 U.S.C. § 103(a) as being unpatentable over GUENA in view of SEDER.

As noted above, GUENA fails to disclose flexible elements and flexible elements structured and arranged to straighten out when positioned to maintain a

position of the plug. Further, Applicants note that GUENA likewise fails to provide any teaching or suggestion of forming the device with flexible elements.

Likewise, Applicants submit that, while SEDER discloses a lacrimal duct occluder, there is no teaching or suggestion of flexible elements, as recited in at least independent claim 1, nor is there any teaching or suggestion of structuring and arranging flexible elements to straighten out when positioned to maintain a position of the plug, as recited in at least independent claims 1 and 19.

Because neither document teaches or suggests at least the above-noted feature of at least independent claims 1 and 19, Applicants submit that no proper combination of these documents can render unpatentable the instant invention.

Further, Applicants submit that claims 16, 17, 22, and 23 are allowable at least for the reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claims 16, 17, 22, and 23 and indicate that these claims are allowable.

Application is Allowable

Thus, Applicants respectfully submit that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. §§ 102 and 103, and respectfully request the Examiner to indicate allowance of each and every pending claim of the present invention.

Authorization to Charge Deposit Account

The undersigned authorizes the charging of any necessary fees, including any extensions of time fees required to place the application in condition for allowance by Examiner=s Amendment, to Deposit Account No. 19 - 0089 in order to maintain pendency of this application.

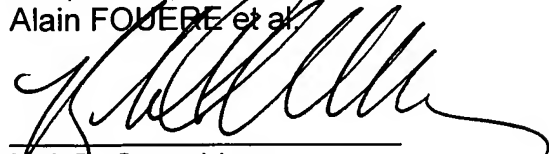
CONCLUSION

In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious the Applicants' invention, as recited in each of claims 1 – 23. The claims have been amended to eliminate any arguable basis for rejection. In addition, the applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

Respectfully submitted,
Alain FOJERE et al.



Neil F. Greenblum
Reg. No. 28,394

Robert W. Mueller
Reg. No. 35,043

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